EXHIBIT V

EXHIBIT
Abbott 1109
7/15/08 gw
PENGAD 800-631-6989

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date: September 18, 1986

Refer to: DPO-R6-3:NS
DR 15

From: Health Care Financing Administration
Region VI - Dallas

Subject: Limits on Payments for Drugs - Proposed Rule
File Code BERC-356-P

To: Director
Bureau of Eligibility, Reimbursement and Coverage
Attention: BERC - 356-P

HCFA
REGULATIONS STAFF OFF
1986 SEP 22 AM 11: 24

We are submitting the following comments regarding the proposed rule on limits on payments for drugs:

GENERAL

1. We support the requirement that alternative methodologies and assurances must be in the approved State Plan.

2. The State of Texas has implemented stringent EAC policies and has not experienced a drop in provider participation. The State of Washington has not experienced any loss of providers and implemented an aggressive EAC program several years ago. Therefore, we believe provider non-participation may not be as big a problem as projected.

3. The proposal indicates that there is a minimum of insurance subsidy. We are not sure what is meant by "minimum". On the average, about 20 percent of a pharmacist's business is third party pay (Drug Topics - June 1984). Generally, third party payment is fast and lucrative for pharmacists. In Massachusetts and Michigan for example, almost 50 percent of pharmacies' business is third party pay.

4. The flexibility allowed States under CIP would require additional Federal oversight to assure that aggregate limits are not exceeded if States choose a mixture of reimbursement patterns including CIP. CIP would be labor intensive on both States and HCFA from this standpoint.

PHARMACISTS' INCENTIVE PROGRAM (PhIP)

1. Reimbursement will continue to be based on the average wholesale price (AWP) even though the lowest AWP is utilized. Depending on the drug, the AWP is highly inflated above what the drug actually costs the pharmacist. This is especially true for generic drugs. This proposal would add 150 percent of an already inflated AWP to the amount which would be reimbursed by Medicaid. Also, the use of the AWP is a process which is too easily manipulated by the industry.

2. PhIP does not consider State laws on substitution of drugs.

COMPETITIVE INCENTIVE PROGRAM (CIP)

1. "Retail price" needs to be defined. Our experience has shown that retail prices are not stable because pharmacists operating in the retail market charge various prices for the same drug/same quantity to different customers, as demonstrated by usual and customary charge (UCC) reviews. There are two factors among several that pharmacists view as important in setting retail prices (a) competitive flexibility - i.e., ability to change pricing depending on whether the product is slow-turnover, price leader, discount or "full-margin" price; and (b) optimum return on investment. Consider also that retail price in most cases exceeds AWP (suggested list price).

2. The CIP alternative is not specific on the levels of discounts which would be applied. As soon as you start considering "a small discount or fee screen" you get into the same bind as we now face, i.e., "What should be the difference between AWP and actual cost from a reimbursement standpoint?"

3. CIP would require States to build and maintain UCC profiles as well as prevailing screens by locality. This would generate tremendous administrative costs above the costs now incurred by States for pricing drugs. Texas estimates that it would require eight professional people plus support staff four years to implement CIP (i.e., define policy, collect pricing data, computer transition, hold workshops for providers, etc.) in that State.

4. We do not believe five to ten percent off retail is consistent with common trade practices. This is shown in the OIG's report as well as reviews conducted by HCFA Regional Offices nationally. Is the five to ten percent discount based on a study? The discount should be based on data already collected and should be more reflective of what the pharmacist pays for a drug product.

5. The mandatory discount of 25 percent off the retail price of brand name drugs for reimbursement of multi-source drugs is insufficient. Data exist which reveal that generic drugs are marked up anywhere from 25 to 150 percent.

6. The article states that mark-ups on both brand name and generic drugs are similar. This is not true. As stated above, reviews have shown that mark-ups on these drugs vary drastically.

7. Most States do not do UCC audits as required by regulation. The elimination of survey costs, for example, announces that we accept whatever the market will bear. While screens are computationally simple, obtaining the information to develop the screens is a tremendous labor intensive task and the volume is enormous. Also, States do not generally collect data on UCC as assumed here. Not all States require providers to bill the UCC.

8. By basing payment on retail prices, CIP might in some instances encourage pharmacists to increase their prices to the general public to obtain optimum Medicaid reimbursement.

9. The reimbursement requirements for CIP are not as simple as appears in this proposal. As an example, verification of true retail prices would be extremely labor intensive. Retail pricing is complex and varied.

10. If a State believes the profit margin on retail prices under CIP is unacceptably high, there is no provision to curb reimbursement.

DISPENSING FEES

Under each of the three proposals, dispensing fees have not been specifically addressed. We believe the fee setting guidelines contained in 42 CFR 447.333 results in inconsistent and sometimes illogical fee setting methods and unjustified fee increases.

As requested in the proposed rules, I am submitting comments on dispensing fees in the form of the attached option paper.

If you have any questions, please let me know.

J. D. Sconce
Regional Administrator

Attachments

EXHIBIT W

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456
Civil Action No. 01-12257-PBS

Hon. Patti Saris

THIS DOCUMENT RELATES TO:

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc. and Hospira, Inc.

CIVIL ACTION NO. 06-11337-PBS

DEFENDANT ABBOTT LABORATORIES INC.'S RESPONSES TO VEN-A-CARE OF THE FLORIDA KEYS, INC.'S SECOND SET OF INTERROGATORIES

Defendant Abbott Laboratories Inc., ("Abbott") responds to Ven-A-Care of the Florida Keys, Inc.'s ("Ven-A-Care") Second Set of Interrogatories ("Requests") as follows:

GENERAL OBJECTIONS, OBJECTIONS TO INSTRUCTIONS AND DEFINITIONS

1. Abbott objects to Ven-A-Care's wholesale incorporation of Sections I (Instructions) and II (Definitions) of the United States' First Set of Interrogatories, served on Abbott on November 17, 2006. Such a wholesale incorporation is improper because they are unduly confusing and do not assist Abbott in answering the Interrogatories below. Subject to and without waiving any objections, Abbott incorporates its Objections and Responses to Sections I and II, which were part of Abbott's Responses and Objections to the United States' First Set of Interrogatories that were served on January 5, 2007, as well as any other Objections and Responses asserted against the same Instructions and Definitions served upon Abbott during the course of this litigation.

INTERROGATORY

3. State whether you contend that the Court lacks jurisdiction over the instant cause of action, or any part thereof, based upon the "public disclosure" provisions of 31 U.S.C. § 3730(e)(4); and, if so, identify and describe with specificity:

a. each public disclosure or disclosures;

b. the time and date of each public disclosure or disclosures;

c. The particular information (including drug product, NDC, reported or transactional pricing information, marketing practices, inducements, or price reporting practices) that you contend was "publicly disclosed" in each of the public disclosure or disclosures;

d. the source or sources of the public disclosure or disclosures including, but not limited to, whether each public disclosure was of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media;

e. all facts and information which you contend supports any contention by you that any part of the instant action was "based upon" the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media.

The time scope of this interrogatory is not limited to the time period of January 1, 1985 to the present and any response should include any "public disclosure", regardless of time period, that is responsive to this interrogatory.

ANSWER: In addition to its General Objections, Abbott objects to this Interrogatory because it is overly broad, unduly burdensome, and seeks information protected by the attorney client privilege, work product doctrine, and/or any other applicable privilege or doctrine. Abbott also objects to this Interrogatory because it seeks information not in the custody or control of Abbott and/or is either in the possession of Ven-A-Care or in the public domain. Abbott also objects because the terms "contend," "action," "disclosure," "aware," "relates," "relating," "allegations," "transactions," "criminal," "civil," "administrative," "hearing," "congressional," "Government [General] Accounting Office report, hearing, audit, or investigation," and "news media" are vague and ambiguous.

Abbott also objects because the scope of the Interrogatory goes beyond the inquiry permitted by the District Court's September 17, 2008 order, which limited Ven-A-Care to an "interrogatory asking Abbott whether it contends there are any public disclosures." With the exception of the phrase "State whether you contend that the Court lacks jurisdiction over the instant cause of action, or any part thereof, based upon the "public disclosure" provisions of 31 U.S.C. § 3730(e)(4)," Ven-A-Care's interrogatory falls outside the Court's order.

Subject to and without waiting its objections, and consistent with the Court's September 17, 2008 order, Abbott states as follows: Abbott contends that there are public disclosures in this matter. Pursuant to the Court's order, Ven-A-Care is now obligated to respond fully to Abbott's Interrogatory No. 20 within fourteen (14) days after this response is served.

Counsel for Ven-A-Care has taken the position that the Court's order requires Abbott to provide a wide range of details regarding the public disclosures of which Abbott is now aware. Abbott disagrees with that position. In the spirit of cooperation, however, Abbott will, to the current extent of its knowledge, identify the evidence showing that Ven-A-Care's allegations were publicly disclosed. In so doing, however, Abbott does not consent to any attempt by Ven-A-Care to limit its response to Abbott's Interrogatory No. 20 by responding only to the public disclosures identified herein, or by offering legal argument as to the sufficiency of the public disclosures identified. Any such response by Ven-A-Care would violate Judge Bowler's August 20, 2008 order, affirmed by the District Court on September 17, 2008, which rejected Ven-A-Care's request to limit its responses to specific public disclosures that Abbott might identify.

Contrary to Ven-A-Care's position, the law makes clear that, should Abbott establish that Ven-A-Care's allegations were publicly disclosed, Ven-A-Care will be required to establish that it "is an original source of [its] *own allegations* under the exacting standard of 31 U.S.C. §

3730(e)(4)(B)," but not that it is an original source of the publicly-disclosed allegations. *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 378-79 (D. Mass. 2008) (Saris, J.) (emphasis added). Accordingly, Abbott is currently entitled to discovery of the *facts* that Ven-A-Care would offer to establish that it was an "original source" of, and had "direct and independent knowledge" of, its *own allegations*. Ven-A-Care's response to Abbott's Interrogatory No. 20 must therefore state the factual basis which would support any argument by Ven-A-Care that it received the information contained in its allegations "directly" (*i.e.*, "through [its] own efforts without an intervening agency") and "independently" (*i.e.*, through a source which is not, itself, a public disclosure). *See id.* at 379.

Subject to the foregoing objections and limitations, Abbott contends that deposition testimony and documents produced in this case demonstrate that the allegations on which Ven-A-Care's claims are based were the subject of extensive discussion, debate, investigation and other public disclosure throughout the 1990s. Accordingly, Abbott incorporates into this response, and refers Ven-A-Care to, the deposition transcripts, including exhibits, of witnesses who have testified in this case, including, for example, Zachary Bentley, Mark Jones, Luis Cobo, John Lockwood, Paul Chesser, David Tawes, Robert Vito, Bruce Vladeck, Nancy-Ann Min deParle, Thomas Scully, Cody Wiberg, and Leo Sullivan. Abbott further refers Ven-A-Care to the documents produced by the Government, Ven-A-Care and third parties evidencing the fact that the allegations of the case against Abbott were the subject of government investigation and public discussion before those allegations were made against Abbott. For example, Abbott incorporates into this response the work papers and other documents produced by the Government relating to the studies performed by OIG in 1991, 1994 and 1999 in a successful effort to quantify the prices paid by pharmacies for drugs reimbursed by Medicare and Medicaid.

By way of further example, Abbott incorporates into this response the documents gathered, generated and produced by Ven-A-Care as part of its investigation prior to filing a lawsuit against Abbott, including publicly available pricing catalogs, website pages and communications to and from Congress and other government officials.

The attached Exhibit 1 provides a list of evidence showing that Ven-A-Care's allegations in this matter were publicly disclosed. The evidence contained on Exhibit 1 is based upon Abbott's current knowledge and research into potential sources of public disclosure. Although Abbott believes that the evidence contained on Exhibit 1 is more than sufficient to show that the allegations on which the case against Abbott is based were publicly disclosed, Abbott further notes that the United States' inordinate delay in deciding to intervene in this matter has prejudiced Abbott's ability to locate and identify any and all pertinent public disclosures.

This response is subject to modification and supplementation, based, *inter alia*, on Abbott's continuing research and Ven-A-Care's responses to Interrogatory No. 20.

November 3, 2008

By: /s/ David S. Torborg

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EXHIBIT X

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume I

Washington, D.C.

Thursday, January 24, 2008

9:00 a.m.

Page 242

book or something?
MR. TORBORG: I think it's dated on the side 1996.
MS. MARTINEZ: Right. I'm just saying for the record, we're not going to have an exhibit, so --
MR. TORBORG: Sure. That's a good idea. I'll do that.
BY MR. TORBORG:
Q. Ms. Gaston, do you recognize that book?
A. Yes.
Q. Okay. Could you tell us what it is?
A. It's the FDA Orange Book.
Q. It's a hard copy version dated 1996?
A. Correct.
Q. And the FDA publishes its Orange Book once every year; is that right?
A. I'm not sure.
Q. Okay. In any event, this one at the side says it's 1996?
A. Correct.
Q. And is it your understanding that the

Page 243

Orange Book has different sections, one of which is titled Product Drug Cost Listing or something like that? If you look at the top page there.
A. Are you talking about in here? It's been years since we've I've looked at one of these books, so --
Q. If you look at the spot that I showed you, where your finger is, what does the top of that say? I can't remember exactly.
A. "Prescription drug product list."
Q. Do you know what that means?
A. Prescription drug product list.
Q. So that's a list of prescription products in the Orange Book --
A. Okay.
Q. -- by alphabetical order? Is that what it looks like?
A. That's what it looks like.
Q. And looking at vancomycin hydrochloride there, there are a number of different manufacturers listed; is that right?
A. Correct.

Page 244

Q. Which manufacturers are there?
MS. MARTINEZ: Excuse me. Just for the record, could we have -- again, since we have no exhibit, could we have the page that she's looking at, page number for the record?
THE WITNESS: 3-302.
A. Fujisawa, Lilly and I think that's it.
Q. Can I take a look at that real quick?
A. Mm-hmm.
Q. Did you see one for Abbott?
A. Oh, okay. You're over here too. It's also on page 3-303. Is this a continuation over here of this?
Q. That's the way that I read it, but --
MS. MARTINEZ: Since we can't see what --
A. Okay. Ledderle, it looks like they're in here too. Abbott, Elkins. Okay. That's it.
Q. Now, based on your understanding, are there any of those vancomycin products that are not rated A?
A. It doesn't appear that way.
Q. So under the regulatory and statutory

Page 245

criteria vancomycin hydrochloride would qualify as a drug product that would satisfy the FUL criteria; is that right?
MR. WINGET-HERNANDEZ: Objection, form.
MS. MARTINEZ: Objection, form.
A. I would say no, because -- just because it's A-rated. This is an injection.
Q. Okay.
A. So I don't know if this product -- if this is an injectable, then there are certain products that are in the included on the FUL.
Q. And we'll talk about that in a bit. Why don't we talk about it now. Why are not injectable products included on the FUL?
MR. WINGET-HERNANDEZ: Objection, form.
A. When I started to work on the FULs injectable products were not included. And it's my understanding that the purpose of the FUL program is to set reimbursement rates on drugs that are generally used by the Medicaid population in an outpatient-type, like a pharmacy-type setting, most commonly used products. And it's my understanding

Page 246

that injectables and other products many times are provided in a physician's office and other type of settings where they might not be claimed separately. They might be included in a payment, like a physician payment.

Also, injectables, many times when they're billed on the claim form they're not -- they're billed with codes rather than NDC numbers, which means that the states may not be paying for them through their pharmacy benefit but through another means, such as a physician's visit or a hospital or something like that.

So many times what we're trying to do with the FULs is use most commonly used drugs and covered outpatient drug type, so like tablets and capsules.

Q. Is there anything in the regulations or statutes that limit the FUL program to tablets or capsules or other drugs that are commonly administered in the outpatient setting?

A. Not that I know of.

Q. That was just the -- when you started

Page 247

working on the FULs that was just the way that HCFA approached it, you did not establish FULs on the injectables?

A. Correct.

Q. And did you ever receive any explanation about why that was?

A. I can't say specifically there was an explanation. I think you learn this as you work with the program.

Q. But you would agree with me that the Orange Book page that I showed you does show that in 1996 there were at least two versions of vancomycin that were rated A in the Orange Book?

A. Correct.

MS. MARTINEZ: Objection, form.

Q. And so -- I want to get back to this computer business. Was the computer program specifically designed to not include injectables or how did that work?

A. You'd have to talk to the data folks. We were not including injectables. I don't know what criteria they put in there.

Page 248

Q. Because if the initial identification of drugs that satisfied the criteria was just two or more A-rated drugs or three or more A-rated drugs if one of them was not A-rated, and that was done by computer presumably that would bring in injectable drugs like vancomycin, right?

MS. ALBEE: Objection.

A. No. There are still more criteria. You still have the Orange Book criteria, but there are still criteria that the systems folks put in to look for the type of drugs that the FUL prices are set on.

Q. So is it your understanding that HCFA specifically set up the computer program to identify and exclude injectable drugs?

MS. MARTINEZ: Objection, form.

A. In one part of the process, yes.

Q. And do you know in what part of the process that was done?

A. No, I don't.

Q. Did you have any part in that process of either manually excluding the injectables drugs or

Page 249

setting up a computer program such that those drugs would be moved aside?

A. The basic criteria for the system was developed before I got there.

Q. Who would be the best person to ask about why it was that injectables were specifically excluded from the FUL program?

MR. WINGET-HERNANDEZ: Objection, form.

MS. MARTINEZ: Objection, form.

A. I don't know. Pete Rodler was the first one I know that worked on FULs. That's the only person I could think of.

Q. Are these other -- now, we've talked a little bit about Exhibit 462 that talks about the Orange Book data. And we talked about the criteria already, correct? And now you've identified I think another criteria, which is to exclude injectable drugs, right?

MS. MARTINEZ: Objection, form.

A. Correct.

Q. Is that criteria written down anywhere?

MR. WINGET-HERNANDEZ: Objection, form.

Page 262

Q. And OBRA '93, that would be referencing what?
A. It's the Social Security Act. It amended the Social Security Act, just like OBRA '90 established section 1927, OBRA '93 made amendments to section 1927.
Q. OBRA was a statute passed by Congress?
A. Yes.
Q. Omnibus Reconciliation Act?
A. Correct.
MS. MARTINEZ: Maybe Omnibus Budget Reconciliation Act?
MR. TORBORG: Did I not say that?
MS. MARTINEZ: It has OMB.
MR. TORBORG: Oh. I'm sorry. Omnibus Budget Reconciliation Act.
BY MR. TORBORG:
Q. And was it your understanding that Congress had mandated HCFA to establish federal upper limits for any multiple source drugs that met specific criteria?
MS. MARTINEZ: Objection, form.

Page 263

Q. Right?
A. Correct.
Q. Congress had told HCFA you must do this?
MS. MARTINEZ: Objection, form.
Q. Is that right?
A. Congress amended the law to include this.
Q. But the mandates means that HCFA was mandated by law to establish federal upper limits for multiple source drugs that met specified criteria, correct?
MS. MARTINEZ: Objection to form.
A. If that's what the legislation does, yes.
Q. Have you ever reviewed the legislation?
A. What do you mean reviewed?
Q. Have you looked at it?
A. Yes.
Q. The actual statute itself?
A. Yes.
(Exhibit Abbott 463 was marked for identification.)
BY MR. TORBORG:

Page 264

Q. Let me explain what this document is. This is a section of the Omnibus Budget Reconciliation Act of 1990. And I've included a cover page which has the title as well as a section 4401 titled Reimbursement of Prescribed Drugs. That's what this is. I have not given you the entire OBRA 1990.
I'd like you, if you would, to go eight more pages from the page you're at now. I'm sorry it doesn't have page numbers on this. But it would be a section F, pharmacy reimbursement. Were you able to find it?
A. Yes.
Q. And under section 2 it says establishment of upper payment limits. Do you see that?
A. Yes.
Q. And then it says "HCFA shall establish a federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically equivalent and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such

Page 265

and shall use only such formulations when determining any such upper limit." Do you recall reviewing this language before?
A. Yes.
Q. Now, this statutory criteria does not discuss any criteria relating to injection drugs or infusion drugs; is that right?
A. It doesn't specify any drugs in particular.
Q. It just says "all multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent," correct?
MR. WINGET-HERNANDEZ: Objection to form. You've misread it, Counsel.
MR. TORBORG: I'm sorry. I'll read it again.
BY MR. TORBORG:
Q. "HCFA shall establish a federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent."

Page 266

Did I read that right?
A. Yes, you did.
Q. Now, this indicates that HCFA shall establish it for each multiple source drug. And I think we saw earlier in looking at a copy of the 1996 Orange Book that for vancomycin there were three or more drugs that were therapeutically and pharmaceutically equivalent, correct?
MS. MARTINEZ: Objection to form.
A. Correct.
Q. And you indicated that if that was an injection drug it would not have met the -- it would have been knocked out of the FUL process by the computer; is that right?
A. Correct.
Q. And is that consistent with the statutory language here?
MR. WINGET-HERNANDEZ: Objection, form.
MS. MARTINEZ: Objection, form.
A. The language doesn't go into that type of detail in the statute.
Q. It doesn't talk about excluding injection

Page 267

or infusion drugs, does it?
A. No, it doesn't.
Q. Do you recall any discussions about that issue while you were at HCFA, whether or not the statutory or regulations governing the federal upper limit allowed HCFA to exclude injectable or infusion drugs?
A. I don't -- no. I don't remember specific discussions like that.
Q. You just know that for as long as you've been working on it it's just been something that's been excluded at the outset?
A. Exactly. Yes.
Q. And you have some understanding of why that is, but you weren't there originally when the decision was made?
A. Correct.
Q. You've just been told about this rationale over time?
A. Right. I understand the rationale. It's been explained to me.
MR. TORBORG: What time do people want to

Page 268

end today? We've been going for I think an hour or more. I could continue to go until 5:00 if people want to stop at 5:00. And that's what I would recommend that we do, go another 25 minutes. Or since we started a little bit late, if people want to go past 5:00 I could take a break now.
MR. WINGET-HERNANDEZ: I would prefer to go to 5:00 for what it's worth.
MR. TORBORG: I think that probably makes more sense.
MS. MARTINEZ: Yeah. I vote for going to 5:00 and stopping, cutting out the break if everybody can take it.
THE WITNESS: That's fine.
MR. TORBORG: Is that okay?
THE WITNESS: Mm-hmm.
MR. TORBORG: Okay.
THE VIDEOGRAPHER: I have 25 minutes remaining.
MR. WINGET-HERNANDEZ: That's enough. That takes us to 5:00.
MR. TORBORG: That will be perfect. All

Page 269

things are coalescing into a decision to go.
MS. MARTINEZ: Counsel, could I just request that at some point you make a copy of the pages that the witness looked at in the FDA drug book and we can just --
MR. TORBORG: Mark it as an exhibit maybe?
MS. MARTINEZ: Well --
MR. TORBORG: Let's talk about it and deal with it at the end of the deposition.
MS. MARTINEZ: Yeah. But if you could PDF that or something.
MR. TORBORG: Yes.
BY MR. TORBORG:
Q. Now, is it your understanding that the federal regulations for FULs had an aggregate test? Do you understand what I mean by that?
A. I do. The test part confuses me.
Q. The states' compliance with federal upper limits was measured in the aggregate, correct?
A. Yes. Correct.
Q. Could you explain to us as best you can

EXHIBIT Y

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL	:	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	:	CIVIL ACTION
PRICE LITIGATION	:	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:	
U.S. ex rel. Ven-a-Care of	:	Judge Patti B. Saris
the Florida Keys, Inc.	:	
v.	:	
Abbott Laboratories, Inc.,	:	Chief Magistrate
No. 06-CV-11337-PBS	:	Judge Marianne B.
		Bowler

Page 366

subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of --
A. As of October 2003.
Q. That's correct, isn't it?
A. I guess it is. That's what the statute says. Another piece of sausage. I have just forgotten that we did that, to be honest with you, which I assume is why they don't have a dispensing fee for anything but respiratory drugs, because they didn't do that for respiratory drugs.
Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion, has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?
MR. GOBENA: Object to the form. The legislation speaks for itself.
MR. BREEN: Objection to the form.
BY MR. DALY:
Q. You can go ahead.
A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed

Page 367

by members. I'm sure the staff -- staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.
Q. And are you aware of whether the drugs that DOJ is suing Abbott for, many of those drugs are used in the home infusion context and using DME?
MR. GOBENA: Objection to form.
THE WITNESS: As of today, I'm aware of it. I wasn't aware of it before.
BY MR. DALY:
Q. But as of today, you are?
A. Yes. Obviously looking at the drug list.
Q. Page 27 of Exhibit Abbott 191, which is your 10-3 -- yes, your October 3 -- excuse me, October 3, 2002 testimony. I just want to direct you

Page 368

to page 27.
A. 27?
Q. Yes.
A. Okay.
Q. And in your testimony in response to Mr. English, you indicate that you think -- well, you state, "I think there are a lot of different provider areas that may have small impacts from AWP, and we are certainly willing to work with the committee to identify those." And then you mentioned oncology as -- oncology and dialysis and hematology being sort of the big three, right?
A. Yes.
Q. And then you say, "I think almost every physician to some degree that administers drugs probably has some beneficial cost shifting benefit from AWP, I think those are the three big areas," you see that language?
A. Yes.
Q. And that was a true statement, correct?
A. Yes.
Q. On page 31, I just want to get a fix for

Page 369

-- and we may have covered this in some part in the sort of background section that we did at the beginning, but you state at the bottom of the page, "I had been working on Medicare for over 20 years and there has never been any law passed more complicated than this one." How far back does your work on Medicare go?
A. In a minor way, probably 1982. But in a full time way, 1989.
Q. And what were you doing with respect to Medicare in 1982?
A. Not much. Occasional staff work for Senator Gorton, but very, you know, minor.
Q. And '89 would have started your work with the Bush Administration?
A. And OMB. Yes.
Q. And if you would turn to page 34. If you -- actually, if you look at 33, the page before, it looks like you finished up your testimony, and then George Reeb, R-E-E-B, got in the hot seat. And began to talk a little bit about Medicare and Medicaid. And on page 34 of Mr. Reeb's testimony, he states

EXHIBIT Z

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

- - - - - - - - - - - - - - - - -

IN RE: PHARMACEUTICAL	) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	) CIVIL ACTION
PRICE LITIGATION	) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)
U.S. ex rel. Ven-a-Care of	) Judge Patti B.
the Florida Keys, Inc.	) Saris
v.	) Chief Magistrate
Abbott Laboratories, Inc.,	) Judge Marianne B.
No. 06-CV-11337-PBS	) Bowler

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(captions continue on following pages)

Videotaped deposition of Kathleen Buto

Volume II

Washington, D.C.

Thursday, September 13, 2007

9:00 a.m.

Page 308

the physician did not incur any costs for the drug."

Was there any connection between the removal of the 15 percent discount on AWP to concerns about shortfalls in administrative payments and the need to cover other costs associated with the administration of drugs?

A. I'm looking at -- if you'd give me a couple seconds here, I'm looking at the response. Because I don't recall that that was the reason. But let me just look and see what we said in response to that comment. (Reading).

It looks to me as if we dodged the question. In other words, they didn't respond one way or the other to whether that was at a reason for going to the alternative methodology. And I'm sure we discussed it. As a general matter, not related per se to this issue, the government doesn't like to pay for some things under one mechanism that was intended for one use and sort of overpay there in order to compensate for other costs.

Page 309

In reality it happens. It looks to me as if what we decided to do is avoid that whole issue, but try to say, okay, here's a compromise approach that we think will address general concerns about the 85 percent but also get us where we want to go, which is to pay accurately for drugs that Medicare is paying for. And that would be the survey approach that the carriers would use and the estimated acquisition cost or the actual acquisition cost.

Q. You stated in your answer that you thought you dodged the question, right?

A. Yup.

Q. Is it your experience during your time at HCFA that there were times when HCFA did not put its -- all of its rationales in its decision-making in a published document such as a regulation?

A. No, I wouldn't say that. I would say that if we thought the response and the change in the regulation addressed the concern we would basically put that out there as the overall

Page 310

response to a range of comments on an issue. So basically what the oncologists were saying was this was an unfair cut.

Our response, we're going to go back to 100 percent of AWP and for high volume drugs we're going to look at a methodology for going after actual acquisition costs. So that was believed to be a valid response to the overall concerns about the cut.

Q. Are HCFA's determinations and rationales for decisions that they make or don't make always in a published document?

A. Well, you know, I can only speak to my experience. We would try to to the best of our ability respond to the comments that were raised. It may not be every specific, but the rationale for taking the position is what we tried to put in responses to comments. So always? You know, I can only speak from my own experience.

Q. But this was a situation where the oncologists, perhaps others, had raised the issue that the 15 percent was perhaps too much of a

Page 311

cut. And those were concerns that you heard, correct?

A. Right.

Q. And you responded to?

A. Right. In the final policy.

Q. And you would agree with me that this particular regulation -- and I think you said earlier by using the word "dodge" -- doesn't exactly articulate that rationale?

MR. DRAYCOTT: Objection. You can answer.

A. My reason for using that word was we didn't directly answer the question, but we answered the question.

Q. By the policy?

A. By the policy.

Q. So the policy itself sort of demonstrated what HCFA's thinking was itself?

A. Yes. The policy responded to the range of comments we got, in our view.

Q. If I could ask you to go back to Exhibit Abbott 299. That was the public comment

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EXHIBIT AA

REVIEW OF MEDICAID DRUG STATE PLAN AMENDMENTS

Although there are no statutory provisions for payment rates for Medicaid drugs, states are required to set rates in accordance with regulations at 42 CFR 447.301-333.

BACKGROUND

Estimated Acquisition Cost (EAC) and Dispensing Fee

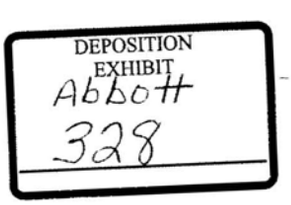
There are two components of this payment rate and each is required to be determined separately. The first is EAC, which simply means the cost to the pharmacy of obtaining the drug. The second is the dispensing fee, which is the pharmacy's direct and indirect cost of dispensing a drug. This includes everything from packaging to pharmacy overhead costs such as the electricity and salaries. Each component is measured separately. The ingredient cost is defined in 42 CFR 447.301 as the state "...agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers." Dispensing fees are simply required to be "reasonable". The regulations require that the agency's payment methodology for prescription drugs be described "comprehensively" in the state plan.

In practice we have told states that wish to modify their EAC levels that they must provide a factual basis to support a change in the EAC or dispensing fee. One method to support a change in EAC is to audit an appropriate number of pharmacies to determine current acquisition costs.[1] We have told the CMS Regional Offices (RO) that in reviewing state plan amendments (SPAs), they should compare rates for contiguous states rates as well as other states in the region. We have also said that they should consider drug cost studies. For the dispensing fee, we have said states could establish a reasonable fee by: (1) audits and surveys of operational costs; (2) compilation of data regarding professional salaries and fees; and (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc. For dispensing fees, we have told the regional offices that they could, among other things, compare the proposed change to the related price indices, e.g. the Consumer Price Index (CPI).

Office of Inspector General (OIG) Reports and State Submitted Audits

Recently issued OIG reports indicated that the actual acquisition cost of brand name prescription drug products nationally is an average of AWP less 21.84 percent. Recent discussions with the OIG indicate that they will further refine this number to differentiate it between those single source (brand name drugs) without generic competition and those with innovator multiple source (brand name drugs) with generic competition. The OIG indicates that the single source drugs will likely show an average discount of around 17% and the innovator multiple source drugs of around 24%. The OIG also studied generic

[1] States usually base the EAC on Average Wholesale Price (AWP) levels with a significant discount e.g. AWP less 10%.



drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is an average of AWP less 65.93 percent.

State studies vary on the level of discount and while an exact level of discount cannot be determined, they appear to average in the range of 20% to 35% off of AWP.

ANALYSIS

In recent months there has been an increase in SPAs proposing to change the reimbursement methodology (a listing of these SPAs is attached). Where there are surveys of costs, the findings generally show that these State's reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels. The lesser level of discount is generally the result of negotiations that occur between the state and pharmacy representatives after the survey results are known. In other cases, the states legislature have responded to the escalating costs of Medicaid drugs by enacting legislation that increases the discount in the ingredient cost or the dispensing fee of these drugs. Legislation usually does not address why these rates are the best estimates or are reasonable.

It is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements. Accordingly, we believe an analysis and an acceptance of other factors states are now using to establish payment rates should be considered in looking at the EAC and the dispensing fee.

We think that the first part of our review should be continuing to rely on the existing review criteria (i.e. survey and rates in other states). For EAC, we would continue to look to surrounding states or because we now think that payment rates vary little nationwide, to a nationwide average. We think it is also helpful to strongly consider approval where the direction of the state's proposed level of reimbursement represents a program savings that does not appear to affect pharmacy participation. Finally, we think EAC needs to include a broader measure of factors that would result in a state agency's best estimate. We could consider the actions of the legislature or negotiations that result in a lower payment rate, even if that rate may differ from other documentation, such as a state survey.

Because the requirements to set dispensing fees are less specific, we would continue to allow states greater flexibility here. For instance, we would permit states to reduce these fees not only to reflect lower costs; but also to permit states to increase them to encourage other program savings measure, such as allowing a higher dispensing fee for the use of generic drugs.

Apart from that, we think a longer-range look at the OIG and state studies as well as a reevaluation of current regulations are in order. If, in fact, there needs to be another basis, such as nationwide surveys that can establish these rates, we need to look at the feasibility and impact of doing so.

HHC004-0189

OPTIONS

(The following options are for approvals of SPAs, denials would be determined on a case-by-case basis)

For ingredient costs –

Approve SPAs that **decrease** the ingredient cost as long as it is no lower than that of another state, which has not experienced a significant decline in pharmacies (proxy measure for access).

Approve SPAs that **decrease** the ingredient cost as long as it is no lower than the levels of costs found by the OIG (i.e., approximately 17 % for single source, 24% for innovator multiple source, and 65.93 % for generics).

Approve SPAs to **increase** payment for ingredient costs if they are less than the median nationally.

Approve any rates set in state statute.

For dispensing fees –

Approve SPAs with higher dispensing fees for generics.

Approve SPAs with dispensing fees **increase**s when the proposed fee is less than the national median.

Approve SPAs with dispensing fee **decreases** when the proposed fee is no less than what is paid by any other state (proxy measure for access).

RECOMMENDATIONS

We recommend that we implement all of the above options. On SPAs that did not meet the above criteria, we would not automatically disapprove that SPA. We would look at the individual circumstances in the state as well as its supporting documentation and rational to decided whether to approve the SPA.

DECISION

Approve _____ _____ Disapprove _____ _____
Signature Date Signature Date

EXHIBIT BB

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DATE: OCT 2 2 2002

TO: Thomas A. Scully
Administrator

Ruben J. King-Shaw, Jr.
Deputy Administrator and Chief Operating Officer

FROM: Director
Center for Medicaid and State Operations

SUBJECT: Review of Medicaid Drug State Plan Amendments—**DECISION**

We are writing to seek your approval for criteria to be used for reviewing state plan amendments (SPAs) that seek to change the payment rates for drugs. There are no explicit statutory provisions for payment rates for Medicaid drugs. States are required to set rates in accordance with regulations at 42 CFR 447.301-333.

BACKGROUND

Estimated Acquisition Cost and Dispensing Fee

There are two components of this payment rate. The first is Estimated Acquisition Costs (EACs), which means the estimated cost to the pharmacy of buying the drug. The second is the dispensing fee, which is the pharmacy's direct (e.g., packaging costs) and indirect (e.g., rent, electricity) cost of dispensing a drug. Each component is defined separately. The ingredient cost is defined in 42 CFR 447.301 as the state "...agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drugs most frequently purchased by providers." Dispensing fees must be "reasonable." The regulations require the state to describe the agency's payment methodology for prescription drugs "comprehensively" in the state plan.

In practice, we have told states that wish to modify their EAC levels that they must provide a factual basis to support a change in the EACs or dispensing fee. One method to support a change in EACs is to audit an appropriate number of pharmacies in order to determine current acquisition costs.[1] We have told the CMS regional offices (ROs) that in reviewing SPAs,

[1] States usually base the EAC on Average Wholesale Price (AWP) levels with a significant discount, e.g., AWP less 10 percent.

RELEASED

they may compare rates for contiguous states as well as for other states in the region. We have also said that they should consider drug cost studies. For the dispensing fee, we have said that states may establish a reasonable fee by: (1) conducting audits and surveys of operational costs; (2) compiling data regarding professional salaries and fees; and (3) analyzing compiled data regarding pharmacy overhead costs, profits, etc. For dispensing fees, we have told the ROs that they may, among other things, compare the proposed change to a related price index, e.g., the Consumer Price Index.

Office of Inspector General (OIG) Reports and State Submitted Audits

Recent OIG reports estimate the actual acquisition cost of brand name prescription drug products nationally to be, on average, the average wholesale price (AWP) less 21.8 percent. The OIG recently refined this number to differentiate it between those single source brand name drugs without generic competition and those innovator multiple source brand name drugs with generic competition. The OIG estimates that the single source brand name drugs cost, on average, AWP less 17.2 percent and the multiple source brand name drugs cost AWP less 24.4 percent. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is, on average, AWP less 65.9 percent. Industry sources indicate that nationally, higher profit margins are obtained on generic prescription drug products.

State studies vary on the level of discount but generally are in the range of AWP less 20 percent to 35 percent.

ANALYSIS

In recent months, there has been a significant increase in the number of SPAs proposed which would change the reimbursement methodology. State cost surveys have generally showed that state reimbursement could be reduced by a percentage greater than the proposed AWP discount levels. The discount has usually been reduced as the result of negotiations between the state and pharmacy representatives after the survey results are known. In other cases, the state's legislature has responded to the escalating costs of Medicaid drugs by enacting legislation to increase the discount in the ingredient cost or decrease the dispensing fee. Legislation usually does not address the basis for the ingredient cost reduction or the reasonableness of the dispensing fee.

It is proving increasingly difficult to require states to provide statistical data to support their proposed payment rates. In addition, we believe that other sources of information and other factors can be used to evaluate the appropriateness of payment rates.

As an alternative to requiring states to provide surveys or statistical data to support their proposed rates, we would ask states to compare their proposed rates to those of other states. For EACs, we would broaden our comparisons from surrounding states to all states because the market for drugs is national. In order to provide states with current payment rates of other states, we will maintain a list of each state's current EACs and dispensing fees on the CMS Web page. (For dispensing fees, we will put more weight on other states in the region, as these costs may

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differ by geographic cost differentials.) In short, we will look favorably on proposals to reduce reimbursement when there is a basis to conclude that the reduction will not affect pharmacy participation.

Finally, we will approve rates set by the legislature or through negotiations, even if the rate differs from that suggested by other documentation, such as the rates of other states or from a state survey.

Because the regulations on dispensing fees are less specific (i.e., the standard is "reasonableness"), we would continue to allow states greater flexibility here. For instance, in addition to allowing states to reduce these fees to reflect lower costs, we would also permit states to increase or vary their rates in order to provide incentives to pharmacists to dispense less costly drugs, such as by allowing a higher dispensing fee for dispensing generic drugs.

OPTIONS

The following options are for approvals of SPAs; denials would be determined on a case-by-case basis.

For ingredient costs (EACs) –

1. Approve SPAs that **decrease** the ingredient costs as long as the costs are no lower than those of any other state that has maintained adequate pharmacy participation.

2. Approve SPAs that provide an aggregate **decrease** in the ingredient costs as long as the costs are no lower than the levels of costs found by the OIG (i.e., approximately 17 percent for single source, 24 percent for innovator multiple source, and 66 percent for generics), as long as the state can demonstrate adequate access.

3. Approve SPAs to **increase** payment for ingredient costs if the costs are less than the national median.

4. Approve rates set in state statute provided they meet one of the above three criteria.

For dispensing fees –

1. Approve SPAs with higher dispensing fees for generics.

2. Approve SPAs with **increases** in dispensing fees when the proposed fee is less than the national median.

3. Approve SPAs with **decreases** in dispensing fees when the proposed fee is no less than what is paid by any other state.

RELEASED

RECOMMENDATION

We recommend that we implement all of the above options. On SPAs that did not meet the above criteria, we would not automatically disapprove that SPA. We would look at the individual circumstances in the state as well as its supporting documentation and rational to decide whether to approve the SPA.

Dennis G. Smith

DECISION

Approve _____ _____
Signature Date

Disapprove _____ _____
Signature Date

RELEASED

EXHIBIT CC

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COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT – DIV I
CIVIL ACTION NO. 04-CI-1487

COMMONWEALTH OF KENTUCKY
ex rel. JACK CONWAY, ATTORNEY GENERAL — PLAINTIFF

v.

ALPHARMA USPD, INC., *et al.* — DEFENDANTS

AGREED ORDERS ON MOTIONS *IN LIMINE*

On behalf of the Commonwealth of Kentucky and Defendant Sandoz Inc. ("Sandoz"), Sandoz submits the following Agreed Orders on Motions *in Limine* for the above captioned case. Both parties conferred and agree to the language contained in the eleven (11) orders below.

1. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO EXCLUDE THE FIRST DATABANK DEFINITIONS OF AWP

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is DENIED.

2. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO PRECLUDE MISLEADING EVIDENCE ABOUT AWP "SPREADS"

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is DENIED.

3. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO EXCLUDE UNAUTHENTICATED CVS DOCUMENT

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is GRANTED. Plaintiff's Trial Exhibits 1736, 1905, 2023, 2188, 2276, 2378, 1737, and 1906 and references thereto, including deposition testimony concerning such documents, are excluded.

4. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL DOCUMENTS

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is GRANTED IN PART and DENIED IN PART as follows:

1. Motion to exclude the email from Christopher Worrell regarding Ribavirin, (Plaintiff's Trial Exhibits 1667, 2034, 2172, 2236, and 2290) is DENIED.

2. Motion to exclude the email chain regarding Albertsons and Alprazolam (Plaintiff's Trial Exhibit 2308) is GRANTED IN PART and DENIED IN PART. Plaintiff shall redact the language addressed in Sandoz' motion, and all references to the redacted portion, including in deposition testimony, are excluded.

3. Motion to exclude outdated letters to out of state pharmacies (Plaintiff's Trial Exhibits 1000, 1894, 2086-2090, 2367) is GRANTED IN PART and DENIED IN PART. Plaintiff shall be permitted to introduce only one such letter at trial.

4. Motion to exclude comments from Generic Pharmaceutical Association on a proposed rule (Plaintiff's Trial Exhibits 1452 and 2447) is DENIED AS MOOT, in light of the Court's ruling regarding AMP evidence.

5. Motion to exclude the AmeriSource Letter (Plaintiff's Trial Exhibits 2029, 2129, and 2233) is GRANTED. Plaintiff's Trial Exhibits 2029, 2129, and 2233 and references thereto, including deposition testimony concerning such documents, are excluded.

5. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO PRECLUDE THE COMMONWEALTH FROM ATTRIBUTING THE MONETARY AND PRICING ACTIVITIES OF ANOTHER MANUFACTURER (APOTHECON) TO SANDOZ

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion regarding Plaintiff's Trial Exhibits 1738, 1739, and 1740 is DEFERRED until Plaintiff seeks to introduce such evidence through deposition testimony. Plaintiff shall provide advance notice of its intention to use such documents so as to permit Sandoz sufficient opportunity to raise its concerns regarding admissibility with the Court. The Motion is MOOT as to Plaintiff's Trial Exhibits 2146, 2283, 2286, and 2289, based on Commonwealth's representation that it does not intend to use these documents at trial.

6. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO PRECLUDE CERTAIN DEPOSITION TESTIMONY DESIGNATED BY PLAINTIFF

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is MOOT IN PART, DENIED IN PART, and DEFERRED IN PART as follows:

1. Motion to exclude deposition testimony of Frank Stiefel is DENIED.
2. Motion to exclude deposition testimony of Charles Kinney and Shawn Brown is DENIED IN PART AS MOOT and DEFERRED IN PART. Plaintiff shall not introduce Kinney and Brown's testimony as it relates to AMP, in light of the Court's ruling excluding AMP evidence used to prove government knowledge of Sandoz' prices. All other objections are deferred until trial, based on Plaintiff's representation that it does not plan to use such deposition testimony given the Court's ruling excluding such AMP evidence. Plaintiff shall provide advance notice of its

intention to use such testimony so as to provide Sandoz sufficient opportunity to raise its concerns regarding admissibility with the Court.

3. Motion to exclude deposition testimony of Neil Warren is MOOT. Plaintiff has withdrawn Neil Warren as a potential witness.

7. DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO DISMISS CERTAIN OF THE COMMONWEALTH'S CLAIMS, TO PRECLUDE EVIDENCE IN SUPPORT OF SUCH CLAIMS, AND TO STRIKE IMPROPER REQUESTS FOR DAMAGES

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is DENIED.

8. THE COMMONWEALTH'S MOTION *IN LIMINE* RELATING TO SANDOZ' USE OF DEPOSITION TESTIMONY AT TRIAL

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is DENIED IN PART and DEFERRED IN PART as follows:

a. The Motion with respect to Patricia Kay Morgan is DENIED.

b. The Motion with respect to the deposition of Debra Bahr is MOOT given the Commonwealth's agreement with Sandoz regarding the designation of Debra Bahr as a 30.02 witness, except objections regarding whether certain testimony is within a noticed topic are reserved for trial.

c. The Motion with respect to the depositions of Betty Barber, Kurt Godshall, Neville Wise, and federal government employees, including Paul Chesser and Cynthia Hansford is DEFERRED.

d. All other issues raised in the Motion are MOOT.

9. COMMONWEALTH'S MOTION *IN LIMINE* TO EXCLUDE TESTIMONY REGARDING "CROSS-SUBSIDIZATION" OF LOW DISPENSING FEES, OR PHARMACIES LEAVING THE MEDICAID PROGRAM

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is GRANTED IN PART and DENIED IN PART with instructions as follows:

a. Parties shall be permitted to introduce evidence of cross-subsidization;

b. Parties shall be permitted to introduce evidence that pharmacy participation in the Medicaid Program was a concern; and

c. Expert witnesses shall be precluded from opining about whether pharmacists would have left the Kentucky Medicaid program if reimbursement was lowered to actual acquisition cost.

10. COMMONWEALTH'S MOTION TO EXCLUDE GOVERNMENT KNOWLEDGE EVIDENCE

Having considered the parties' briefs and arguments in support of and in opposition to the Motion, IT IS HEREBY ORDERED that the Motion is DENIED.

11. DEFENDANT'S DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF GREG HAMILTON

The Motion is MOOT as to Sandoz. Plaintiff has withdrawn Mr. Hamilton as a rebuttal expert from Sandoz' trial. A separate order will be filed with respect to AstraZeneca and GlaxoSmithKline.

This ____ day of June, 2009.

_____

ROGER L. CRITTENDEN, SPECIAL JUDGE
FRANKLIN CIRCUIT COURT

AGREED TO:

/s/ Vincent R. FitzPatrick Jr.
Vincent R. FitzPatrick Jr. (admitted *pro hac vice)*
Wayne A. Cross (admitted *pro hac vice*)
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/s/ *C. David Johnstone*
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Madison, WI 53711
(608) 661-8855
(608) 661-0067 FAX

Counsel for Plaintiff,
Commonwealth of Kentucky

CERTIFICATE OF SERVICE

I, Stefan Mentzer, hereby certify that on this ___ day of June 2009, I have caused a copy of the foregoing AGREED ORDERS ON MOTIONS *IN LIMINE* to be served on all counsel of record by causing the same to be posted to LexisNexis File & Serve, pursuant to Paragraph 7 of Case Management Order No. 1.

/s/ Stefan Mentzer
Stefan Mentzer

EXHIBIT DD

ENTERED
FEB 10 2009
FRANKLIN CIRCUIT COURT
SALLY JUMP, CLERK

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION 1
CIVIL ACTION NO. 04-CI-1487

COMMONWEALTH OF KENTUCKY,
Ex rel. JACK CONWAY, ATTORNEY GENERAL **PLAINTIFF**

v.

ALPHARMA USPD, INC., et al. **DEFENDANTS**

* * * * * * * * * * * * * *

This matter is before the Court upon the Defendants' Joint Motion for Summary Judgment on All Claims. The standard established for this Court in its determination is contained in *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc.*, 807 S.W.2d 476 (Ky. 1991). The Kentucky Supreme Court, in *Steelvest*, said that for the court to grant a motion for summary judgment, "the movant must convince the court, by the evidence of record, of the nonexistence of an issue of material fact" and "the movant should not succeed unless his right to judgment is shown with such clarity that there is no room left for controversy."*Id.* at 482.

The essence of the Defendants' motion is twofold. One is that the publishing or causing to be published Average Wholesale Prices (AWP) for individual drugs knowing the Commonwealth of Kentucky is using those prices to determine Medicaid reimbursement levels for pharmacists is not deceptive or a fraudulent act or false advertising when those published prices have no relation to actual average prices. The Defendants maintain the established AWP's are "benchmark" prices with "benchmark"

remaining undefined. The second and more persuasive argument is that even though the published AWP's bore no relation to actual prices, there was no deception because the Commonwealth of Kentucky was not deceived concerning the fact that AWP did not represent an actual number. The Defendants argue, supported by affidavits and deposition testimony, that many Kentucky officials in the Medicaid Program, in the policy-making levels of the Executive Branch, and in the General Assembly knew that AWP did not mean actual price. Additionally, the Commonwealth was informed of this fact by the United States Government and the Commonwealth's own studies contained in the Myers & Stauffer reports. The Defendants argue that this knowledge is reflected in the State's policy to reimburse pharmacists at a rate of AWP minus 10% and AWP minus 12%. The Defendants also point out that in order to participate in the Medicaid Program the manufacturers were required by the federal government to provide rebates to the Commonwealth. So any excess costs paid by the State of Kentucky on the front end were recouped on the back end.

The Commonwealth argues that it was a deceptive practice to publish, under the term "Average Wholesale Price" a number that was virtually meaningless. The State also argues it was unable to make informed reimbursement decisions because accurate cost data was controlled by the Defendants and AWP was manipulated for the benefit of the Defendants. The Myers & Stauffer studies concluded that AWP's were 18% to 20% higher than actual average prices.

The Defendants have framed the questions appropriately: 1. Was the Commonwealth deceived? and 2. Was reimbursement to Kentucky pharmacies inflated due to the Defendants' misconduct or based on well-informed policy choices?[1]

The Court is led to one conclusion. The legal arguments of the parties are all based upon arguable facts or at least arguable inferences from established facts. There is a question of fact whether the publishing of AWP was a routine trade or deceptive practice. There is little question that the policy makers in the Medicaid Program knew that AWP did not represent actual price. There are questions, however, whether there was any relationship of AWP to actual costs,[2] whether state officials knew the relationship of AWP to actual costs, and whether reimbursement levels would have been different if AWP had represented the actual Average Wholesale Price.

There are genuine issues of material fact to be determined and the Defendants are not entitled to judgment as a matter of law. CR56.03.

The Defendants' Joint Motion for Summary Judgment on all Claims is **DENIED.**

So **ORDERED** this 10th Day of February, 2009.

Roger Crittenden, Special Judge
Franklin Circuit Court

[1] Defendants' Reply Memorandum in Further Support of Their Joint Motion for Summary Judgment on All Claims, p. 15.
[2] Reference is made to the "2 x 4" analogy where "2 x 4" is a well-understood trade term in the construction industry for a board that has the dimensions of 1&1/2" by 3&1/2." In the instant case there is a factual question whether AWP had the same meaning for all parties.

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STATE OF WISCONSIN **CIRCUIT COURT BRANCH 9** **DANE COUNTY**

STATE OF WISCONSIN,

Plaintiff,

v. Case No. 04 CV 1709

ABBOTT LABORATORIES, et al.

Defendants.

FILED
MAY 20 2008
STATE OF WISCONSIN
CIRCUIT COURT FOR DANE COUNTY

DECISION AND ORDER ON PLAINTIFF'S MOTIONS FOR PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANTS NOVARTIS, ASTRAZENECA, SANDOZ, AND JOHNSON & JOHNSON

OVERVIEW

Plaintiff State of Wisconsin moves for partial summary judgment against defendants Novartis, Astra Zeneca, Sandoz, and Johnson & Johnson on the liability issues in its first two claims for relief in the Second Amended Complaint premised upon §100.18(1) and §100.18(10)(b), Stats., respectively. All defendants oppose the motions, and have responded with summary judgment motions of their own. This decision will resolve only the state's motions; defense motions will be addressed in a subsequent decision.

The parties have submitted evidentiary materials and written briefs both for and against the plaintiff's motions, and no party has requested oral argument. Accordingly, the motions are ripe for resolution.

For the following reasons, the motions are denied. The court, however, dismisses **"Count II-- Violation of Wis. Stat. §100.18 (10) (b)"** of the Second Amended Complaint, merging it into **"Count I-- Violation of Wis. Stat. §100.18(1)"**, as more fully explained below.

SOME INITIAL CONSIDERATIONS UNDER §802.08, STATS

Section 802.08, Stats., provides in pertinent part:

> "(1) Availability. A party may ... move for summary judgment on any claim, counterclaim, cross-claim, or 3rd-party claim which is asserted by or against the party. ...
>
> (2) Motion. ... The judgment sought shall be rendered if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages."

(Underlining added).

At the outset, several considerations pertinent to plaintiff's motions arise under the statute.

First, the motions against the four defendants purportedly seek summary judgment on the issue of liability alone, and then only with respect to two of the state's five claims. Accordingly, whether or not to grant summary judgment is discretionary with the court, given the statute's specific inclusion of the word "may" for partial versus "shall" for full summary judgment. *See, e.g., City of Wauwatosa v. Milwaukee County*, 22 Wis. 2d 184, 191, 125 N.W. 2d 386, 389-90 (1963). Presumably, if there is no genuine issue as to any material fact and the law indisputably favors the movant, the court should exercise its discretion to grant interlocutory partial summary judgment on liability only in those circumstances where to do so would "secure the just, speedy and inexpensive determination of [the] action and proceeding." §801.01 (2), Stats.[1] More on this below.

Secondly, what does §802.08 (2), Stats., mean by "liability"? Of particular relevance to plaintiff's motions, does "liability" include cause? If so, the state's motions must be denied outright, because they expressly and quite candidly do not purport to resolve the causation issues under §100.18, Stats. The summary judgment statute itself is not entirely clear on this point, although it suggests that causation is part of "liability", since partial summary judgment is permissive in those circumstances where there remains a "genuine issue as to the amount of damages." Usually the "amount of damages" is not even a relevant consideration until causation is decided. That is to say, rendering interlocutory summary judgment on liability where only the *amount* of

[1] Section 801.01 (2), Stats., provides "... Chapters 801 to 847 shall be construed to secure the just, speedy and inexpensive determination of every action and proceeding."

damages remains to be determined presupposes resolution of the causation issues in the liability analysis.[2]

Caselaw is also less than instructive. In *Physicians Plus Ins.Corp v. Midwest Mutual Ins. Co.,* 254 Wis. 2d 77, 101 (2002), for example, causation was held necessary to establish liability. But *Physicians Plus* is a public nuisance case, and thus less than compelling in its applicability to our case. This is especially true considering that the Supreme Court there upheld a partial summary judgment even though the issue of causation was remanded for trial along with the damages issues. The Supreme Court thus appears unperturbed by the question raised here, which accordingly will be considered no further. More specifically, this court accepts, while not entirely convinced, that it could exercise its discretion to grant partial summary judgment on liability issues in this case notwithstanding genuine material factual issues concerning causation.

APPLYING PARTIAL SUMMARY JUDGMENT METHODOLOGY UNDER §802.08, STATS.

The prescribed summary judgment methodology is well-described in *In re Cherokee Park Plat,* 113 Wis. 2d 112, 115 *et seq.* (Ct. App. 1983):

> "Summary judgment is governed by sec. 802.08, Stats. Its purpose is to determine whether a dispute can be resolved without a trial. Summary judgment methodology must be followed by an appellate court as well as the trial court. *Board of Regents v. Mussallem*, 94 Wis. 2d 657, 674, 289 N.W 2d 801, 809 (1980).
>
> Under that methodology, the court, trial or appellate, first examines the pleadings to determine whether claims have been stated and a material factual issue is presented. If the complaint (in these consolidated cases, the notice of the appeal to the circuit court) states a claim and the pleadings show the existence of factual issues, the court examines the moving party's affidavits for evidentiary facts admissible in evidence or other proof to determine whether that party has made a prima facie case for summary judgment. To make a prima facie case for summary judgment, a moving defendant must show a defense which would defeat the claim. If the moving party has made a prima facie case for summary judgment, the court examines the affidavits submitted by the opposing party for evidentiary facts and other proof to determine whether a genuine issue exists as to any material fact, or reasonable conflicting inferences may be drawn from the undisputed facts, and therefore a trial is necessary. *Grams v. Boss*, 97 Wis. 2d 332, 338, 294 N.W. 2d 473, 476-77 (1980).

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[2] Even beyond this frolic into §802.08(2) esoterica is the question of whether or not partial summary judgment on liability can ever be appropriately granted where, as here, the remedies sought do not include common-law "damages", but are purely equitable. See Second Amended Complaint, pages 31-32, and §100.18 (11) (a), Stats. (enforcement actions to be commenced and prosecuted "in any court having equity jurisdiction.") Because the state's motions are decided on other grounds, we need gnaw this bone no further.

> Summary judgment methodology prohibits the trial court from deciding an issue of fact. The court determines only whether a factual issue exists, resolving doubts in that regard against the party moving for summary judgment. *Grams*, 97 Wis. 2d at 338-39, 294 N.W. 2d at 477."

Analyzing the state's Second Amended Complaint under this methodology, plaintiff's first claim for relief based on §100.18(1), Stats., ("COUNT I") is legally sufficient, while the second claim for relief under §100.18 (10) (b) Stats.,("COUNT II") is not.

On the first claim, the Court rejects the defense contention that §100.182, not §100.18(1), is the appropriate and exclusive statutory remedy for plaintiff's claims. Plaintiffs allegations relate to fraudulent pricing, while §100.182 is targeted at entirely different types of fraudulent drug advertising, such as deceptive or misleading representations material to the effects of the drug, physical or psychological effects associated with the use of the drug, and deceptive resemblances to controlled substances. Accordingly, defendants cannot fashion a successful defense patterned after *Gallego v. Wal-Mart Stores Inc.,* 288 Wis. 2d 229 (Ct. App. 2005), which featured a global statute prohibiting fraudulent advertising specific to food that, unlike §100.182, largely mirrors a more generic §100.18(1) in the types of conduct prohibited,

As for plaintiff's second claim for relief, §100.18(10)(b) does not create a separate claim for relief, but merely defines one species of conduct that is deceptive and therefore remediable under §100.18(1), Stats. Accordingly, the second claim ("COUNT II") is dismissed, and any conduct by defendants which the state proves transgresses §100.18 (10) (b) will be considered under the first claim for relief.

Finally, the court rejects without further comment the defense position that separation of powers principles prohibit judicial enforcement of §100.18(1) in this case, because the legislature has expressly granted this court jurisdiction in equity to address violations of the statute under §100.18(11), without in any way restricting its reach to pharmaceutical pricing.

THE STATE'S PRIMA FACIE CASE

While varying in the particulars against each of the four target defendants, plaintiff presents evidence broadly supporting its contention that defendants, in marketing their drugs, falsely reported both wholesale acquisition costs ("WACs") and average wholesale prices ("AWPs") to third parties, such as First DataBank and Red Book, knowing that these third parties would publish pharmaceutical pricing information relied upon by the state in paying or reimbursing retail providers of the drugs through the Wisconsin Medicaid program. The misrepresented WACs and AWPs caused the third parties to publish artificially high drug prices which, in turn, caused, and still causes, the Wisconsin Medicaid program to overpay for defendants' drugs. A *prima facie* case for partial summary judgment on liability under §100.18, Stats., is thus presented.

DEFENDANTS' RESPONSE TO THE STATE'S EVIDENCE

Defendants present a number of factual and legal arguments against the state's motions, some with merit, some without. The arguments without merit are easily dispatched.

First, defendants argue that providing false information to third parties with whom defendants are in a contractual relationship, such as First DataBank, does not qualify as a misrepresentation to "the public", which is required for liability under §100.18(1), Stats. While defendants' argument is correct as far as it goes, it is beside the point. Section 100.18(1) prohibits not only direct misrepresentations to the public, but misrepresentations which defendants "cause, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state..." The thrust of plaintiff's *prima facie* case is that, by reporting false prices to third parties, defendants indirectly (and perhaps directly) caused dissemination of misrepresented drug prices to the public, including Wisconsin Medicaid, through the third parties' publications. That defendants had contracts with the third parties is no defense.

Secondly, and closely related, the argument (made by at least one defendant) that no misrepresentation was made "in this state", as required for liability under §100.18(1), ignores these third party publications distributed here.

Thirdly, the defense argument and evidentiary submissions demonstrating that the misrepresentations caused the state no damage would be material if plaintiff were seeking a full summary judgment on its first claim for relief. However, because plaintiff has moved only for partial summary judgment on limited issues concerning liability (excluding causation), they are not directly on point. Nonetheless, because the causation element appears, to the court at least, to require that plaintiff present proof to the fact finder at trial[3] establishing the specific misrepresentations made regarding the particular drugs at issue, granting a partial summary judgment to the extent requested by the state seemingly would accomplish little to further "the just, speedy, and inexpensive determination of the action" [§801.01(2), Stats.] Again, more on this below.

Turning now to the meritorious defense positions, defendants' evidence demonstrates the existence of material factual issues, and competing reasonable inferences derived from the factual record, on whether or not actionable misrepresentations occurred and what role, if any, the defendants played in fomenting these misrepresentations (which, after all, allegedly ripened in third party publications).

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[3] The court deliberately uses the term "fact finder" because, although this case has been scheduled for jury trial(s) commencing in February, 2009, it does not appear that plaintiff's §100.18 enforcement action entitles it to a jury, given its equitable nature under §100.18(11), Stats. *See also State v. Excel Management Services, Inc.*, 111 Wis. 2d 479, 331 N.W. 2d 312 (1983). There is no jury trial right in equitable actions. *Neff v. Barber*, 165 Wis. 503, 162 N.W. 667(1917). The parties' entitlement to jury trial on this and plaintiff's other claims for relief [unjust enrichment also sounds in equity, *see General Split Corp. v. P & V Atlas Corp.*, 91 Wis. 2d 119,124, 280 N.W. 2d 765, 768 (1979)] will be addressed at the next status conference.

On this point, the court accepts that context is relevant to the inquiry, as are any mutual understandings between/among the parties to the representations. At the very least, one cannot, on this record, rule out the relevance of context and mutual understanding to these §100.18 (1) claims.

Plaintiff's argument that "[a]n untrue statement is untrue regardless of whether the listener knows it is untrue" (Plaintiff's Reply Brief, p. 6) begs the question. How is a statement "untrue" in the first place, if the speaker and listener are using terms they mutually understand because they have agreed on their meaning-- that is, they have together developed the definitions, either expressly or tacitly, such that they have a common understanding? If two parties agree that the term "cat" shall be defined to include a "dog", is the definition "untrue" under §100.18(1)? With such agreed terminology, it seems self-evident that representing a "dog" to be a "cat" cannot, years later, expose one party to a legitimate misrepresentation charge by the other, under §100.18(1) or otherwise. This is essentially the defense position in an admittedly oversimplified nutshell.

The state demurs, citing dictionary definitions which, while relevant, are not dispositive. It also contends that there was no agreement on the definition of AWPs and WACs, let alone one to which the state was a party. This latter point may very well be true, but it is not undisputed. This court's function on summary judgment is not to resolve discrepancies in the proof, nor to favor one inference over another. Rather, the court must accept all reasonable inferences emanating from the evidence in favor of the defense, and end its inquiry where, as here, there are disputed material facts or competing reasonable conclusions that can be drawn from the evidence.

SOME ADDITIONAL OBSERVATIONS

Even if the evidence and inferences were undisputed, and the law unequivocally favored plaintiff, it is doubtful the court would exercise its discretion to grant plaintiff the interlocutory partial summary judgment requested. This is because it is difficult to see how doing so would advance the just, speedy, and inexpensive determination of this action, which is the overriding goal under §801.01(2), Stats.

As plaintiff emphasizes, this is an enforcement action seeking to enjoin violation of §100.18, Stats., as well as other appropriate relief. But even if we accept the state's summary judgment position as uncontroverted, what conduct would the court enjoin? As defendants point out, the state's motions are devoid of any particulars concerning which particular drugs are at issue and what specific misrepresentations were allegedly pertinent to each. The statute already generically prohibits the misrepresentations which it addresses, and an injunction by this court duplicating these non--specific statutory prohibitions would add little, if anything, to effective enforcement.

For example, violation of §100.18(10)(b) is perhaps the state's strongest case under §100.18(1). Section 100.18(10)(b) provides:

> "It is deceptive to represent the price of any merchandise as a manufacturer's or wholesaler's price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise."

What efforts would plaintiff be spared at trial were the court to grant partial summary judgment finding that a defendant or defendants violated this subsection? The state would still have to prove specific misrepresentations/deception concerning specific drugs for the court to fashion appropriate, targeted relief, and so that causation could be determined.

Bottom line, how would the interlocutory summary judgment be anything other than an advisory ruling to the effect that *if* plaintiff proves that the wholesaler's price or manufacturers price on a specific drug or drugs was deceptive within the meaning of §100.18(10)(b), *then* §100.18(1) has been violated by the misrepresenting defendant?

In short, the court finds little advantage to the ultimate resolution of this case at trial in rendering the interlocutory summary judgment plaintiff seeks, even if the plaintiff otherwise qualified for such relief (which, again, it does not). On the other hand, granting the motion might very well create an unlevel playing field by enabling plaintiff to suggest to the jury[4], right out of the gate and devoid of all context, that the court has already found defendant(s) in violation of state law and the rest is just details, when we truly cannot know if a violation has occurred until we see the evidence on specific representations regarding specific drugs.

CONCLUSION

Plaintiff State of Wisconsin's amended motions for partial summary judgment on liability against defendants Novartis, Astra Zeneca, Sandoz, and Johnson & Johnson are DENIED. Count II of plaintiff's Second Amended Complaint, purporting to allege a separate claim for relief under §100.18(10)(b), Stats., is DISMISSED and merged into plaintiff's claim for relief under §100.18(1), Stats., in Count I.

Dated this 20 day of May, 2008.

BY THE COURT:

Richard G. Niess
Circuit Judge

CC: Attorney William M. Conley

[4] If all or any part of this case is heard by a jury, advisory or otherwise.

(for immediate service on all parties per
usual practice in this case)

EXHIBIT FF

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337 Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 09-CV-10547; and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698	

UNITED STATES' OBJECTION TO THE PROPOSED SETLEMENT BETWEEN SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION, WARRICK PHARMACEUTICALS CORPORATION AND VEN-A-CARE OF THE FLORIDA KEYS, AND PROPOSED ORDER

Pursuant to 31 U.S.C. § 3730(b)(1), the United States hereby objects to the Settlement Agreement ("Agreement"), as presently drafted, between Schering-Plough Corporation ("Schering-Plough"), Schering Corporation ("Schering"), Warrick Pharmaceuticals Corporation ("Warrick") (collectively "Schering/Warrick") and Relator Ven–A-Care of the Florida Keys (the "Relator"). The United States also objects to the proposed Order Approving Settlement and Dismissal With Prejudice of Schering-Plough, Schering, and Warrick ("Proposed Order"). If approved, the Settlement Agreement would resolve *United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and, Warrick*

Pharmaceuticals Corporation, Civil Action No. 09-CV-10547 (the "Florida Civil Action") and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698 (the "Massachusetts Civil Action").

The Relator initiated both the Florida and Massachusetts Civil Actions under Section 3730(b)(1) which provides that:

> A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C. § 3730(b)(1). Because the Florida and Massachusetts Civil Actions were brought under Section 3730(b)(1), they may be dismissed *only if the Court and the Attorney General give written consent to the dismissal and their reasons for consenting*. For the reasons set forth below, the Government respectfully objects to the dismissal of the Florida and Massachusetts Civil Actions under the terms of the Settlement Agreement and Proposed Order as they are presently drafted.

SUMMARY OF SETTLEMENT AGREEMENT AND PROPOSED ORDER

Based on its review of the Agreement and Proposed Order, the Government understands the salient terms of the Agreement to be as follows. First, Schering/Warrick will pay $55 million dollars (the "Settlement Amount") into an escrow account. Agreement, Paragraph III(1). The Settlement Amount is to be divided among the State of California ("California"), the State of Florida ("Florida"), the Relator, the Relator's counsel, and the United States consistent with the Allocation Agreement to be filed with the Court. Id. at Paragraph III(2). Schering/Warrick was

not consulted about, and had no input into, the allocation of the Settlement Amount. Id.

Second, in exchange for some portion of the Settlement Amount, the Relator, on behalf of itself and the United States, will release Schering/Warrick for all claims it has or could have brought on behalf of the United States "arising out of or related to the Covered Conduct for the Covered Drugs . . . including but not be limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs." Id. at Paragraph III(5). The "Covered Conduct" basically encompasses allegations that between January 1, 1991 through the Agreement's Effective Date, Schering and Warrick knowingly reported or caused to be reported false prices for the "Warrick Covered Drugs" and thereby caused false claims to be submitted to the Medicaid Program. Id. at Paragraph II(F). The "Covered Drugs" include both the "Warrick Covered Drugs" discussed in the Covered Conduct, and "Schering Covered Drugs," as reflected in Exhibit A to the Agreement. Notably, the Covered Drugs encompass not only drugs that were originally pled in both Civil Actions, but also numerous drugs that were not alleged in either Civil Action and that instead will be added to the Florida Civil Action as a condition of the Agreement. Agreement, Paragraph III(7). Attached as Exhibit 1 is a spreadsheet reflecting the drugs currently pled in the Civil Actions versus the Covered Drugs.

Third, the Settlement is conditioned upon the Court (a) resolving any "potential issues concerning the compliance of Schering with the liability standards set forth in the Court's June 21, 2007, decision in MDL No. 1456, (b) conducting an "independent review" of an analysis prepared by Schering of the Schering Covered Drugs as reflected in Exhibit A to the Agreement, and (c) "independently concurr[ing] that neither the WACs nor the AWPs for the [Schering Covered Drugs] constitute false statements within the meaning of the False Claims Act and that

claims for reimbursement based on such WACs and AWPs are neither deceptive nor unfair."

Agreement, Paragraph III(6). Among the findings of fact and rulings of law that the Court must enter as conditions to the Agreement are:

> [T]hat it has long been understood that, historically, the AWPs reported by the national drug pricing compendia (*i.e.,* FDB Bluebook, Redbook, and Medispan) for brand drugs typically represented an industry-wide, formulaic mark-up of 20% or 25% over the wholesale acquisition cost or WAC for that drug. Furthermore, the Court finds that it was widely understood in the industry, by the early 1990's, that some limited discounting off of WAC (typically, 2% to 5%) was generally available for brand drugs . . . .
>
> [T]hat government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price for that drug (measured, conservatively, by Average Manufacturers Price or AMP calculated in accordance with all applicable HCFA/CMS regulations) to constitute a false or fraudulent statement, or to be misleading, deceptive, or unfair . . . .
>
> * * *
>
> [T]hat none of the WACS or AWPs for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive, or unfair . . . .
>
> * * *
>
> That the Relator has not sought to recover Medicaid proceeds for the Schering Covered Drugs where the AWP did not regularly exceed the average selling price by more than 30%; that the "yardstick" approach used by the Relator screened out brand drugs where the AWP was no more than 25% above a non-fictitious WAC and accepted as a "non-fictitious" a reported WAC that was no more than 5% above the drug's average selling price; and that this "approach to the settlement agreement of [the Florida Civil Action] under the False Claims Act to be reasonable and fair . . . .

Proposed Order, ¶¶ 2, 3, 5, 7.

ARGUMENT

At the outset, it is worth emphasizing that the United States does not object to the Parties reaching a settlement on these Civil Actions. The Government's objections are limited primarily to the scope of release as reflected in the Agreement and Proposed Order as they are presently drafted.

1. The Government objects to the Settlement Agreement and Proposed Order to the extent they state or suggest that the Relator may release or dismiss the United States's False Claims Act claims. See Agreement, Para. III(5)("[T]he Relator on behalf of the United States . . . fully and finally release, acquit and finally discharge . . . [Schering/Warrick."). While the Relator may release any claims *it* has or could have asserted on the United States's behalf to the extent that release binds only the Relator, it does not have the authority to actually release *the United States's* claims without the United States's express consent to do so. In other words, only the United States has the authority to release the claims of the United States against Schering/Warrick.

2. The Government objects to the Settlement Agreement and Proposed Order to the extent that they dismiss with prejudice the United States's claims against Schering/Warrick for the federal share of Medicaid damages arising from the Covered Conduct in states other than California and Florida. Although the Government was not privy to the Parties' settlement negotiations, it was provided with data, analyses, and proposed allocation agreement considered by Florida, California and the Relator to support the Settlement Amount. The Government was not provided any information to suggest that the Parties considered, or that the Settlement Amount included money allocable to resolve, the United States's claims for the federal share of

damages arising from Medicaid damages suffered in states other than California and Florida as a result of Schering/Warrick's alleged conduct.

Indeed, the Government declined to intervene against Schering/Warrick, in part, because it knew that several states had sued Schering/Warrick for the Covered Conduct and were presumably pursuing both the federal and state shares of their respective state's Medicaid damages. Here, where the Settlement Amount only pertains to damages suffered in California and Florida, the Agreement should not be allowed to release the United States's claims arising from the Covered Conduct in the other states.

3. The Government objects to the Settlement Agreement and Proposed Order to the extent they result in the dismissal with prejudice of the United States's claims against Schering/Warrick in connection with the Schering Covered Drugs and the Warrick Covered Drugs, except for the albuterol products. The relator never pled these drugs in the Civil Actions and the Government never investigated them (although Schering did provide the Government with its spread analysis on the Schering Covered Drugs (Exhibit A to the Agreement)). Under the qui tam provisions, if the relator intends to add claims beyond those initially pled, the United States has the right to investigate those allegations and make an intervention determination pursuant to the statute. 31 U.S.C. § 3730(b)(2). The relator should not be permitted to avoid the statutory scheme by including claims that have never been pled nor investigated by the United States, and as to which no intervention decision has been made.

Moreover, in the context of this Settlement, the Government will not receive any consideration for the Schering Covered Drugs, or for the Warrick Covered Drugs (except for Medicaid damages suffered in California and Florida). It is for precisely this type of problem

that Congress made the release of the United States's claims conditional upon the approval of the Attorney General. 31 U.S.C. § 3730(b)(1). If the Settlement Agreement and Proposed Order are approved as presently drafted, the United States would be in a worse position than if no qui tam action had been brought at all, at least with regard to the Schering Covered Drugs and some of the Warrick Covered Drugs. The United States should not be required to forego its right to pursue possible actions merely because a relator has brought a qui tam action and then agreed to dismiss it without providing any benefit for the United States.

4. The Government objects to the Parties conditioning the Settlement Agreement upon the Court effectively issuing an advisory opinion on the Schering Covered Drugs. Federal Courts have limited jurisdiction and must resolve actual cases and controversies. *See Overseas Military Sales Corp. V. Giralt-Armada*, 503 F.3d 12, 16 (1st Cir. 2007); *Osediacz v. City of Cranston*, 414 F.3d 136, 139 (1st Cir. 2005). The Constitution's case or controversy requirement prevents federal courts from issuing advisory opinions and "limit[s] the business of federal courts to questions presented in an adversary context." *Giralt-Armada*, 503 F.3d at 17 (quoting *Flast v. Cohen*, 392 U.S. 83 (1968)).

Here, there is no case or controversy in connection with the Schering Covered Drugs. As noted above, the Schering Covered Drugs are not presently pled in either the Florida or Massachusetts Civil Actions. Moreover, if and when the Relator amends the Florida Civil Action to encompass the Schering Covered Drugs– nearly 15 years after the Relator filed the Florida Civil Action– both the Agreement and Proposed Order make it crystal clear that the Relator does not believe and will not allege that the reported WACs and AWPs for the Schering Covered Drugs give rise to False Claims Act liability. In the absence of an actual, or even an

apparent, dispute between the Relator and Schering/Warrick, a judicial ruling on the Schering Covered Drugs is nothing more than an advisory opinion.

The most plausible explanation for why Schering/Warrick seeks such a ruling from the Court is so that Schering/Warrick may use the ruling to influence the outcome of other pending AWP litigation against it, to which neither the Relator nor the United States is a party. It is telling that the Schering/Warrick supports the appropriateness of the Settlement by focusing solely on the Schering Covered Drugs, and fails to even mention the Settlement Amount or whether the federal share of that Settlement Amount is commensurate to the scope of the claims purportedly being released. Under these circumstances the Court should not permit Schering/Warrick to use the settlement of the Florida and Massachusetts Civil Actions to further a litigation objective in other pending cases. Whether the reported prices for the Schering Covered Drugs would support claims under the False Claims Act, or under any other state law, should be resolved in a real case or controversy; not in the present context where the truth-seeking function of the adversary process is absent.

5. Should the Court decide to proceed with independently evaluating the Schering Covered Drugs, the Government objects to the proposed findings of fact and rulings of law for various reasons. First, there is an insufficient evidentiary record before the Court to render any ruling as to the truth or falsity of the prices Schering reported for its branded products. The only "evidence" before the Court is a presentation generated by Schering's counsel. The Court does not have the reported WACs, AWPs, ASPs, or AMPs for the Schering Covered Drugs. The Court does not have any information on how Schering calculated those reported prices and whether they accurately reflected all relevant discounts, rebates and chargebacks. Regarding all

the "Sales at List [prices]," there is no evidence concerning what percentage of those customers received chargebacks or discounts that may have affected the ultimate effective prices. In the absence of such evidence, it would be difficult to make factual findings regarding what the reported prices actually represent, much less whether they were false, fraudulent, misleading, deceptive, or unfair.

Likewise, the Government objects to all the proposed findings of fact regarding the federal payors. The Government does not dispute the Court's extensive knowledge regarding AWP-related matters. Nevertheless, the Parties have not provided an evidentiary basis for the Court to make a factual finding on whether a government payor, such as Medicaid, knew when a published AWP was within 30% of the average selling price or the average manufacturer price, much less considered whether such an AWP is false, fraudulent, misleading, deceptive, or unfair, as suggested in Proposed Order, Para. 3. As the Court is well aware, an extensive amount of discovery has been taken in connection with the three *qui tam* actions in which the United States has intervened. Any findings of fact regarding the government's knowledge or considerations should be made in the context of a fully developed factual record.

CONCLUSION

For the reasons stated above, the United States respectfully objects to the Settlement Agreement and Proposed Order as presently drafted. The United States is willing to work with the Parties to draft an acceptable Agreement and Proposed Order.

Respectfully submitted,

For the United States of America,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Objection to the Settlement Agreement Between Schering-Plough Corporation, Schering Corporation, Warrick Pharmceuticals Corporation and Ven-A-Care of the Florida Keys and the Proposed Order" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Andy J. Mao
Andy J. Mao

Dated: July 21, 2009

Exhibit 1: Comparison of the Drugs Pled in Florida and Massachusetts Civil Actions and those released as part of the Settlement Agreement and Proposed Order

Florida Civil Action Drugs (Fourth Amended Complaint)	Massachusetts Civil Action Drugs (Third Amended Complaint)	"Warrick Covered Drugs" (Exhibit E to Settlement Agreement)	"Schering Covered Drugs" (Exhibit F to Settlement Agreement)
Albuterol Sulfate solution	Albuterol Inhalation Aerosol	Albuterol Sulfate/Albuterol	n/a
		Amoxicillin	Cedax
		Betamethasone	Celestone Soluspan
		Captopril	Clarinex
		Cholestryamine	Claritin
		Cimetidine	Claritin D
		Clotrimazole	Diprolene
		Cromolyn Sodium	Elocon
		Flurbiprofen	Eulexin
		Glyburide	Foradil
		Griseofulvin	IMDUR
		ISMN	IMDUR Tablet
		Labetalol HCL	Intron A
		Mexiletine	K-Dur
		Mometasone Furoate	Lotrimin
		Oxaprozin	Lotrisone

Exhibit 1: Comparison of the Drugs Pled in Florida and Massachusetts Civil Actions and those released as part of the Settlement Agreement and Proposed Order

		Perphenazine	Nasonex
		Potassium Chloride	Nitro-Dur
		Ribavirin	Normodyne
		Selegiline	Peg-Intron
		Sodium Chloride	Proventil
		Sulcrafate Tablets	Rebetol
		Theophylline	Rebetron
			Sebizon
			Solganal
			Temodar
			Theo-Dur
			Trinalin
			Vancenase
			Vanceril